PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/595,977	Confirmation No.:	1136
Applicant	: Mark Ashby et al.		
Filed	: June 14, 2007		
TC/A.U.	: 3773		
Examiner	: Mashack, Mark F.		
Title	: HEMOSTATIC PRESSURE PLUG		
Docket No.	: 1001.2219102		
Customer No.	: 28075		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

CERTIFICATE FOR ELECTRONIC TRANSMISSION: The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 16 day of November, 2010.

By _____
JoAnn Lindman

Dear Sir:

In response to the Final Office Action of August 16, 2010 and the Advisory Action of October 27, 2010, Applicants hereby request a Pre-Appeal Conference and file this Pre-Appeal Conference Brief concurrently with a Notice of Appeal. Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 1, 27, 40-46, and 61-62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,700,277) in view of Hannam et al. (U.S. Patent No. 5,649,959). After careful review, Applicants must respectfully traverse the rejection.

With respect to independent claim 1, the Final Office Action asserts that Nash et al. disclose "a release mechanism 30, 36 including a hemostatic material (Column 2, Lines 1-4) having a bottom surface attached to the top surface near the center of the flexible plug (Fig 3), and a resilient extension member 36, the resilient extension member has a transverse aperture 62

therein and a suture 34 passing through the aperture to secure the suture to the resilient extension member, the release mechanism positioning and releasing the flexible plug intravascularly at the blood vessel puncture site". Applicants respectfully disagree. Instead, Nash et al. expressly teach away from releasing the asserted flexible plug ("element 32 excluding element 52") intravascularly at column 6, lines 26-28, where Nash et al. state: "[i]n order to ensure that no portion of the anchor member can break off and separate from the closure 20 when the anchor member 32 is deployed within the blood vessel..." Thus, plug member 30 does not appear to release anchor member 32 instravascularly, as claimed.

In the Response to Arguments of the Final Office Action, the Examiner asserts that "[t]he release member as discussed below positions the plug intravascularly and releases it from the sheath" (emphasis added). Applicants note that releasing the asserted plug (anchor member 32) from the sheath is not claimed, nor does a sheath appear in the pending claim. Additionally, Applicants note that the asserted release mechanism (plug member 30) does not appear to release anchor member 32 from the sheath, as asserted by the Examiner. Nash et al. appear to describe the operation of the device at column 7, line 28 through column 8, line 55. In particular, Applicants respectfully direct the Examiner's attention to the following passages: column 7, lines 46-50; and column 8, lines 7-10, 16-19, and 28-33. Nash et al. do not appear to disclose that plug member 30 releases anchor member 32, as asserted by the Examiner. Instead, filament 34 appears to pull plug member 30 out of instrument 10 as instrument 10 is retracted. During retraction of instrument 10, filament 34 remains under tension, connecting anchor member 32 to instrument 10 to effect radial deformation of plug 30 under axial compression. Thus, plug member 30 does not appear to release anchor member 32 from the sheath, as asserted by the Examiner. Applicants submit that the only action, function, or structure that appears to "release" anchor member 32 from the sheath is the cutting of filament 34, which does not read on the pending claim. Even if filament 34 is cut, filament 34 still binds anchor member 32 to plug 30, and thus anchor member 32 is not released intravascularly by the asserted release mechanism.

Separately and furthermore, the Examiner asserts that "the suture can be considered "not directly attached to the flexible plug" since the plug can be considered element 32 excluding the portion 52 that engages the suture since the ends and bottom of the element 32 anchor the apparatus to the subject (Fig 9) while portion 52 engages the suture (Fig 19)" (see Final Office Action, page 4). Applicants respectfully disagree.

Nash et al. expressly describe element 52 as a "hemispherical dome-like projection 52 is located at the center of the top surface" (emphasis added), and also expressly state that "anchor member 32 has a generally planar top surface 46". See column 5, lines 60-67. Column 6, lines 5-9 expressly describe a passageway 56 "extends transversely across the member 32 below the projection 52 and close to the bottom surface 48" (emphasis added) and that "filament 34 is threaded through the passageway 56". Accordingly, Nash et al. appear to expressly disclose filament 34 is directly attached to anchor member 32 via passageway 56 which passes through anchor member 32, in contrast to the pending claim. Figures 2, 3, 5, 6, 8, and 9 clearly show that filament 34 passes through passageway 56 within the interior of anchor member 32, below the top surface 46 of anchor member 32, and below dome-like projection 52. While Figure 19 does appear to show that filament 34 may at least partially wrap around projection 52, filament 34 is disposed within passageway 56 at the center of anchor member 32. This is further illustrated by flexible strip 60 (shown in Figure 19 below projection 52 and above passageway 56) which is expressly disclosed as being within anchor member 32 "just under the top surface 46 and above the transversely extending passageway 56". See column 6, lines 30-34.

In the Advisory Action, the Examiner states that "[e]lement 52 does not perform any plugging action. It just engages the suture. The periphery of element 32 actually engages the tissue and plugs the opening. Therefore the suture can be considered not directly attached to the plug." The Examiner appears to be asserting that the suture only engages projection 52, and therefore the suture is not directly attached to the plug. Applicants respectfully disagree and point out that the express disclosure of Nash et al. clearly contradicts the Examiner's statements. As noted above, projection 52 appears to be positioned over or above passageway 56, which is disposed within anchor member 32. Filament 34 is disposed within through passageway 56, and thus must be considered as directly attached to anchor member 32. Additionally, projection 52 appears to extend from top surface 46. As clearly visible in Figures 3, 6, and 9, top surface 46 engages the inner surface of the vessel wall 22. Therefore, the Examiner's statement that the "periphery" of anchor member 32 "engages the tissue and plugs the opening" is at best only partially correct. Applicants submit that one of ordinary skill in the art would not reach the same conclusion as the Examiner in view of the express disclosure of Nash et al.

Accordingly, Nash et al. do not appear to teach at least these limitations of independent claim 1. Hannam et al. do not appear to remedy the shortcomings of Nash et al. in this respect.

Turning to independent claim 40, the Final Office Action asserts that Nash et al. disclose a connector 78 is disposed between the disk and the hemostatic body. While Nash et al. do appear to disclose a spacer member 78 disposed between the flexible disk and the hemostatic body, spacer member 78 does not appear to couple the two elements. Instead, spacer member 78 appears to be just that – a slidable spacer that can be disposed between and spaced apart from the flexible disk and the hemostatic body. As clearly visible in Figures 4-9 and 19, spacer member 78 does not appear to couple the flexible disk to the hemostatic body.

In the Response to Arguments of the Final Office Action, the Examiner asserts that the "term "couple" is a very broad term and element 78 extends between the two elements". Applicants submit that regardless of the asserted broadness of the claim term "couple", MPEP 2111.01 provides the following guidance: "It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003)" and "[w]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."

Applicants submit that the definition applied by the Examiner is outside of the "ordinary" and "customary" meaning of the term. One of ordinary skill in the art would not consider an element (spacer 78) that merely lies between two other elements (anchor member 32 and plug member 30) to "couple" those two elements. Thus the Examiner's assertion that "element 78 extends between the two elements" reads on the claim term "coupling" appears to be improper.

In the Advisory Action, the Examiner further states that the "definition of couple is "something that joins or connects two things". Element 78 physically "joins" and "connects" the two elements (Fig 9)." Applicants must respectfully disagree. One of ordinary skill in the art will certainly recognize that the asserted relationship set forth by the Examiner is not disclosed or suggest by Nash et al. Element 78 clearly does not physically join or connect anchor member 32 to plug member 30, as asserted by the Examiner. Instead, element 78 physically separates anchor member 32 from plug member 30, and would be recognized as such by one of ordinary skill in the art – particularly in view of the express disclosure of Nash et al. See column 9, lines 14-31; column 11, lines 17-19; and column 13, lines 60-62. Accordingly, Nash et al. do not

appear to disclose or suggest a connector disposed between the flexible disk and the hemostatic body, the connector coupling the flexible disk to the hemostatic body, as in claim 40.

For at least the reasons discussed above, Nash et al. do not appear to properly disclose or suggest all of the limitations of independent claims 1 and 40, as is required to establish a *prima facie* case of obviousness. Hannam et al. do not appear to remedy the shortcomings of Nash et al. with respect to claims 1 and 40. Therefore claims 1 and 40 are believed to be patentable over the cited references. Since claims 27, 41-46, 61, and 62 depend from claims 1 and 40 and add additional elements thereto, these claims are also believed to be patentable over the cited references. Applicants respectfully request that the rejection be withdrawn.

Claims 46-49 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,700,277) in view of Hannam et al. (U.S. Patent No. 5,649,959), and further in view of Kensey et al. (U.S. Patent No. 5,441,517). After careful review, Applicants must respectfully traverse the rejection.

As discussed above, Nash et al. in view of Hannam et al. do not appear to properly disclose or suggest all of the limitations of independent claim 40, as is required to establish a *prima facie* case of obviousness. Kensey et al. do not appear to remedy the shortcomings of Nash et al. and Hannam et al. with respect to claim 40. Accordingly, claims 46-49, which depend therefrom and add additional elements thereto, are also believed to be patentable over the cited references. Applicants respectfully request that the rejection be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Withdrawal of the rejections is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: Nov. 16, 2007

Glenn M. Seager, Reg. No. 36,926
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Tel: (612) 677-9050
Fax: (612) 359-9349